I/5589/2023

File No. 20(5)/2022/IPDMS/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

3rd and 5th Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi - 110001

Date: 10th April 2023

OFFICE MEMORANDUM

Subject: Inputs/suggestions given by the stakeholders on IPDMS Ver 2- Reg

The suggestions/feedback received from the stakeholders (FICCI, ASSOCHAM and M/s BSV) have been examined and action taken/ comments of NPPA on the suggestions received are attached as Annexure-I. None of the issues raised in the representations prevent the companies from filing the various forms in the IPDMS ver 2.0. This is for information of all the stakeholders.

Encl: As above.

Signed by Rajesh Kumar T
राजेश कुमार टी
Date: 10-04-2023 13:37:57
Reason: Approved

(Rajesh Kumar T)
Deputy Director
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Annexure I

Issues raised by Federation of Indian Chambers of Commerce and Industry (FICCI)

S. No	Issue	Remarks/ Reasons	Recommendation of FICCI	NPPA Comments
		Name of	Please add	Form I is filed for the

	Form I	formulation is not available in the provided Drop Down. All Therapeutic category as mentioned in NLEM is not reflected		"New Drug" as defined in the DPCO,2013. It is not possible to determine the "New Drugs" that may be approved in the future. However, if the name(s) of the formulation is not available, the user(s) have the option to select the "Other" option provided in the drop-down. There are no missing Therapeutic Categories. However, in case of any missing therapeutic categories, the same may be forwarded to NPPA for updation. Form I is completely functional and companies are submitting it for retail price fixation..
		The field of **'batch no.'** should be made optional in Form-II.	Form-II is a time bound submission to NPPA. At the time of submission companies would not have clarity on batch numbers at an early stage.	Batch Number is a compulsory field as per the Notified Form II. The same cannot be changed unless the forms are amended and it is a policy matter. It is requested to keep policy matters outside the implementation of IPDMS. However, if the Batch

				number is not available or not determined. The user can enter “Not Determined” or Not Available” etc.
		Request to Revise PTR (Inclusive of E.D) and restore the earlier format PTR (Excluding of GST) which is in line with DPCO.	In order to keep the uniformity of reporting of price data to NPPA it is requested to keep the PTR column (Excluding GST).	The form is digitized as per the Notified Form II and amendments in this regard are underway. However, the companies were required to enter “Inclusive of ED but exclusive of VAT” during the pre-GST period. Now, the companies are filing with prices “exclusive of GST”. The companies can continue to do so. The Forms shall be changed once the amendment is carried out.
	Form-II	Request to remove the field of ‘**Plant name**’.	- Company has to upload many products which are manufactured at multiple locations. - At the time of uploading data, capturing data at Plant name wise will be a challenge and this exercise involve updating data product wise. Also, sometimes it is not known that it will get manufactured in one	The Plant name field provided on the webpage acts as a filter so that users can fill the Form-II plant-wise. The facility for the plant-wise Form-II filing is provided based on the earlier suggestions received from the industry. However, as requested now, along

			plant or multiple plants. - Moreover, company would any how provide the plant name while updating the data in Form- V for a given product; this should meet the requirement of NPPA.	with separate plants, the download of data of all plants shall also be given. Further, this is an additional feature and does not hamper the functionality of Form II
		- Companies are unable to get dump of data of all verified SKUs in one go.	- Keeping in view, the ease of the user, it would be appreciated, if product level data is maintained as per earlier format and upload facility should be provided	On the dashboard, there is a facility for downloading the data dump. If any specific company is facing this issue, they may contact the NPPA IPDMS helpdesk on the designated Email.
		-CP of some scheduled drug is not available		417 CPs are updated and the remaining are under updation. However, this is not blocking the functional flow. Even if CP is not showing Form shall get filed.
		Effective Batch Number: As per Para 16 (iii) of DPCO 2013 form II is required to be submitted within 15 days from the revision of ceiling price; further it is compulsory as per IPDMS 2.0 to submit	We request you to not make submission of batch number compulsory in form II under IPDMS 2.0	Please refer to NPPA Comment on Point No 2 above.

		Effective batch number while submitting Form II, this is practically not possible as all new batches of a schedule product can't be manufactured within 15 days of the issue of revised ceiling price based on WPI,		
		- Option of uploading bulk data is not working. Even when the company upload data without special characters like % , still uploading of the bulk data is not working.	- The option of uploading bulk data has to be restored at the earliest keeping in view of the challenges faced by the user on IPDMS 2.0 Portal.	The uploading of bulk data has been tested and is working in both manual entry methods i.e. without the Excel feature and using Excel also. The '%' character is to be avoided while using the Excel option. If any specific company is facing this issue, they may contact the NPPA IPDMS helpdesk on the designated Email.
		- Earlier there was no field of '**Plant name**' and companies could upload data of Form-III in one go. Since this field has been added to form-III, companies have	-It is recommended to maintain data at product level. -Maintaining plant wise record and to extract for past submission is also cumbersome. -Alternatively, It would be ideal to provide	Please refer to NPPA Comment on Point No 4

	Form-III	to fill Form-III, plant wise which is adding on to the burden. - For products manufactured at 2 or more sites, procuring sales data separately for each site is very difficult and tedious task which will add a huge burden on industry.	multiple selection option to the user at the time of filing Form-III.	
		- Earlier there was option to select period (quarter) while uploading Form-III. This option is missing now.	- It is recommended to incorporate this field as it used to be there in IPDMS 1.0 - It will help to pull out Form-III reports quarter wise in future.	If a company has defaulted in filing earlier quarter filings, they can file Form-III for all defaulted quarters in the same Form along with the recently concluded quarter. This feature is already in place and is functional.
11.		Product Name is not visible	PI add function	The notified Form III does not have the field for Product Name. Hence, the web form has been designed as per the notified Form-III.
12.		Unable to view, edit or download Form IV already saved as draft and cannot submit it as well.		The system is tested; the user can submit, view & edit the forms which have been saved as drafts. The user has the facility to download

	Form-IV			the records saved as draft/final submitted forms and take the print out. However, specific cases where a problem is being faced may be shared with a data set/screenshot of the error on n**ppa-ipdms@gov.in**
13.		Data requirement of PTS (incl. of GST) should be changed to PTS (excl. of GST).	- In order to keep the uniformity of reporting of price data to NPPA it is requested to keep the PTR column(Excluding GST) in line with DPCO.	Amendment of Forms in this respect is underway. Currently, the forms are digitized as per the existing notified forms.
14.		Removal of PTS column from Form-V	- Requirement of PTS data is not mandated by DPCO, therefore it is recommended to remove column of PTS in Form V.	Under examination.
15.		Incorporation of '**Batch no. & manufacturing month'** in Form-V.	- In view of compliance and transparency, it would be good if '**Batch no and Manufacturing month'** are restored as in IPDMS 1.0.	The forms are digitized as per the existing notified forms. '**Batch no and Manufacturing month'** is not a field in the notified Form V
16.		Incorporation of **'new drug'** category in Form-V	- Category of **'New Drug'** apart from Scheduled and Non-Scheduled product was existing in IPDMS 1.0 and 2.0. However, in IPDMS 2.0 the 'New	This is a new point that has been raised. However, necessary changes have been incorporated in the system to address the issue raised.

			Drug' category products are not visible at the time of review of products for updating the Form V	
17.	**Form-V**	- Request to remove the field of '**Plant name'**.	- Companies have to upload many products which are manufactured at multiple locations. - At the time of uploading data, capturing data at 'Plant name' wise will be a challenge and this exercise involve updating data product wise. - Moreover, company would any how provide the plant name while updating the data in Form- V for a given product, this should meet the requirement of NPPA. -'New addition of plant name is not user friendly as the same manufacturer may be registered as a Third Party as well Loan License, and since only products of the specific plant are shown, it becomes difficult to file Form V for multiple products.	Please refer to NPPA Comment on Point No 4. Plant in IPDMS refers to Manufacturing Plants, Contract Manufacturing Companies, Country of Import etc. Marketing companies are required to file Forms for each of the Manufacturing companies as per notified Forms in DPCO,2013.
18.		Currently there is no provision to take print of Draft	We request you to add this feature to IPDMS 2.0 & Password	The provision for download of Drafts is provided. The system

		form V.	generated for submission of Form V should be short it should be of 4 digit numeric	was tested again and the same is working. Also, the OTP that gets generated on Form V is of four digit numeric only. This has been implemented 3 Months back.
19.	**Form-VI**	Medical Devices do not have batch numbers but have a serial number	Medical Devices do not have batch numbers but have a serial number which may be random and hence, batch numbers should not be mandatory for the same. It may further be noted that Schedule II of DPCO 2013 does not include the need for batch numbers.	Batch Number is a compulsory field as per the Notified Form VI. The same cannot be changed unless the Forms are amended. However, if Batch number is not available or not determined. The user can enter “Not Determined” or Not Available” etc.
Miscellaneous Issues				
20.	Form	Form I, II, III, IV, V and VI	Unable to modify draft Form's after saving.	This facility was available in Form –III only. However, it has been extended to all the Forms now and implemented
21.	Form	Form I, II, III, V and VI	If manufacturing company is not registered in IPDMS, please allow text box to input manually	The companies not registered on IPDMS may not be filing the requisite forms even as physical forms and may be non-compliant of DPCO requirements. Hence, this provision cannot be provided.
22.			Plant Name is added,	Please refer to Point 4

	Form	Form II, III, V and VI	but it is not compulsory as per Schedule II of DPCO 2013.	and Point 19.
23.	Form	Brand MRP	If a brand is being manufactured at different locations, change in MRP one plant should reflect against all other plants as well since it's the same brand	Companies are required to file Forms for each manufacturer as per Notified Forms. The Band MRP is not mentioned in forms. The forms cannot be changed unless the Forms are amended.
24.				Several requests were received for the addition of the new Bulk Drug/Formulation & Strengths in the IPDMS 2.0. The matter has been examined and it is found that in most of the cases, the formulations are already available however; the companies wanted to add more specific details in the composition and also wanted the same to be reflected in the Form-V. In case of more than 80,000 SKUs, the composition details are available in the system and the same will be auto filled once the

	Product Verification	Bulk Drug	Bulk Drug Option was supposed to be made available, still not reflected in the system.	SKU is selected by the user. Also, the user can modify such auto filled details. It may be noted that the details mentioned in the “bulk drug” may sometimes be a broad category. For example: the bulk drug shown is “Diclofenac” and the user wants the composition to be “Diclofenac Sodium”. In such a case, for adding more specific details pertaining to their product, the users can enter the composition details in “Detailed composition (if any)”. The system has now been upgraded and the “Detailed composition (if any)” will also be reflected in Form-V. In case your SKU is not available in the system, the company can choose the most relevant category in “Bulk Drug”.
25.				Two input text fields as “Medical Device Category as per Import/Manufacturing License:” and “Medical Device Sub-Category as per Import/Manufacturing

	Product Verification (Medical Device)	Column C - Medical Device Category as per list issued by CDSCO	Mismatch between actual license and the category.	License" has been provided on the medical device add product page. The user can enter the actual license category and sub category, if needed, along with categorization as per risk category of CDSCO. The Form VI will reflect the description as import license.
26.	Product Verification (Medical Device)	Column F - Brand Name	Cannot add special character	This has been implemented one month back itself.
27.	Dashboard	Version I Data	Unable to download a distinct form submitted in IPDMS 1.0	In order to download a distinct Form submitted in the earlier version, the user can go to settings>>advance option>>report control panel>>filter result and then select the distinct Form no. and the filtered data will be populated accordingly. Further, for each field the customizable report can be pulled from the dashboard using this feature.
28.				The full data set of version 1 has been migrated to version 2 as it is.

	Dashboard	Version I Data	IPDMS 1.0 data not imported fully.	Any specific issue faced by specific company may be brought to the notice of NPPA on Email - nppa-ipdms@gov.in
29.	Product Details	Production Capacity cannot be calculated for individual products	Can we put Batch size where indicative production capacity or Production Capacity is mentioned	It has been clarified several times in the past that Indicative production capacity may be reported. The production capacity number may be approximate.
30.	Plant Verification and Product Verification	Modification Approval	Any modifications made in plant/product take a while to get approval from NPPA	Plant modifications and Scheduled products modifications are being approved regularly.
31.	Company Registration	Sikkim Companies Act	Companies registered under Sikkim Companies Act have a 3-digit CIN and the site asks for a mandatory 21-digit CIN	Implemented
32.	Plant Verification	Plant Verification	Requested for deletion of the plant, but the plant has not been deleted yet	The requests for deletion are under examination in view of the new NLEM, 2022 and Form–IV requirement. However, this does impact the filing of Forms.
33.	Product Verification	FDCs	Text input is requested as various FDCs are unavailable	Please refer to Point 24.

34.	Product Verification	Strength	Text input is requested as various strengths are unavailable	

Suggestion/Issue(s) by ASSOCHAM and Bharat Serums and Vaccines Limited

S. No.	IPDMS 2.0 Page	Issue	Comment / Suggestion	NPPA Comment
35	Company Registration	Sikkim Companies Act	Companies registered under Sikkim Companies Act have a 3 digit CIN and the site asks for a mandatory 21 digit CIN	Implemented
36	Plant Verification	Plant Verification	Requested for deletion of the plant, but the plant has not been deleted yet	Refer to Point 32
37	Product Verification	FDCs	Text input is requested as various FDCs are unavailable	Refer to Point 24
38	Product Verification	Strength	Text input is requested as various strengths are unavailable	
39	Form	Form I	Name of formulation is not available in provided Drop Down	Refer to Point 1
40	Form	Form I, II, III, IV, V and VI	Unable to modify draft Form's after saving.	Refer to Point 20
41	Form	Form I, II, III, V and VI	If manufacturing company is not registred in IPDMS, please allow text box to input manually	Refer to Point 21
42	Form	Form III	Product Name not visible	Refer to Point 11
43	Form	Form IV	Unable to view, edit or download Form IV already saved as draft and cannot submit it as well.	Refer to Point 12
44	Form	Effective Batch Date	Effective Batch Date is missing in Form V and should be added as per Schedule II of DPCO 2013. This is specially necessary for	Refer to Point 15

			imported formulations which may be manufactured 6 months prior to MRP implementation in the market.	
45	Plant Verification and Product Verification	Modification Approval	Any modifications made in plant/product take a while to get approval from NPPA	Refer to Point 30
46	Form	Form II	CP of some scheduled drug is not available	Refer to Point 6
47	Form	Form V	PTS is not a part of Form V as per Schedule II of DPCO 2013 and should not be included.	Refer to Point 14
48	Form	Brand MRP	If a brand is being manufactured at different locations, change in MRP one plant should reflect against all other plants as well since it's the same brand	Refer to Point 23
49	FOFFM	Form VI	Medical Devices do not have batch numbers, but have a serial number which may be random and hence, batch numbers should not be mandatory for the same. It may further be noted that Schedule II of DPCO 2013 does not include the need for batch numbers.	Refer to Point 19
50	Product Verification	Bulk Drug	Add Bulk Drug Option was supposed to be made available, still not reflected in the system.	Refer to Point 24
51	Form	Form I	All Therapeutic category as mentioned in NLEM is not reflected	Refer to Point 1

52	Form	Form V	New addition of plant name is not user friendly as the same manufacturer may be registered as a Third Party as well Loan License, and since only products of the specific plant are shown, it becomes difficult to file Form V for multiple products.	Refer to Point 4, 9 and 17.
53	Product Verification (Medical Device)	Column C - Medical Device Category as per list issued by CDSCO	Mismatch between actual license and the category.	Refer to Point 25
54	Product Verification (Medical Device)	Column F - Brand Name	Cannot add special character	Refer to Point 26
55	Form	Form II, III, V and VI	Plant Name is added, but it is not compulsory as per Schedule II of DPCO 2013.	Refer to Point 4, 9 and 17
56	Dashboard	Version I Data	Unable to download a distinct form submitted in IPDMS 1.0	Refer to Point 27 & 28
57	Dashboard	Version I Data	IPDMS 1.0 data not imported fully.	Refer to Point 27 & 28

Additional points sent by ASSOCHAM vde Email dated 31/03/2023

S. No.	IPDMS 2.0 Page	Issue	Comment / Suggestion	NPPA Comment
58	Medical Device Registration No. issued by CDSCO	Can't add '-'of '/' –		Refer to Point 26

59	Medical Device category as per the list issued by CDSCO	Mismatch between the actual license and the category.		Refer to Point 25
60	Product Name Specification as per DCGI approval/ Generic Name	Mismatch between the actual license and the category		Refer to Point 25
61	Brand Name	Can't add special characters like -.(etc and numerical digits like 1,2 etc		Refer to Point 23
62	Applicable GST %	For some medical Devices the applicable GST rate is 0 %. But the column is not picking "0 % ".As a result, the Uploading of product details with Excel is not happening and an Error! Data Not Saved is appearing.		Feature already provided. Please fill the GST as "0" only. This has been done ONE month back
63	Form VI	In addition, there is a specific issue for one company "Multiple OTPs get generated with the single request".		The system is tested to generate OTP and it generated single OTP. Specific issues should be reported a t nppa-ipdms@gov.in with dataset/screenshots.
64	Product Addition	Apply WITH EXCEL - we do not have the drop-down in Excel.		Request is accepted. Implemented shortly.
65	Product Addition	Apply WITHOUT Excel option - IVD – not all reagents/controls/calibrators covered in the dropdown.		This is implemented

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66	Plant Addition	Importers Details – Plant details have no place to input. It reflects for Manufactures' details while we select the 'importers' radio button. – refer screen shot.		Resolved.